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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,825	09/12/2003	Thomas Herbert Peterson	134687NV (MHM 15085US01)	7037
23446 7590 11/18/2008 MCANDREWS HELD & MALLOY, LTD 500 WEST MADISON STREET SUITE 3400 CHICAGO, IL 60661			EXAMINER MEHTA, PARIKHA SOLANKI	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 11/18/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/660,825	Applicant(s) PETERSON, THOMAS HERBERT	
	Examiner PARIKHA S. MEHTA	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 2, 3, 7-13 and 22 are objected to because of the following informalities:

Claims 2 and 8 recite functional language unsupported by structure to produce such a function.

Claim 7 is incomplete for lacking any element or structure that is capable of imaging to guide surgery as set forth in the preamble of the claim.

Claims 3 and 9 fails to further limit the structure of the claimed invention. Claims 3 and 9 recite that the strain gauge is within an electrical circuit, which is considered to be an inherent feature of a strain gauge, and the remainder of the claim merely sets forth limitations placed upon the electrical circuit, which is not positively set forth as part of the inventive structure.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

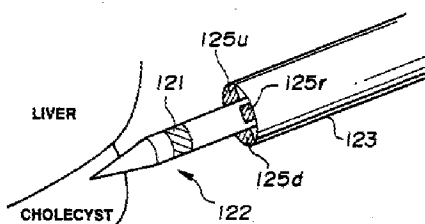
1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kami et al (US Patent No. 5,339,799), hereinafter Kami ('799).

Regarding claims 1, 4 and 6, Kami ('799) discloses a medical instrument comprising a support member 123 operatively connected to a needle-tipped laser probe 122 ("a flexible engaging member having an operative distal tip", wherein "flexible" is interpreted as meaning "capable of being bent") and a strain gauge 121 affixed to an outer portion of the needle, wherein the strain gauge detects movement of the operative distal tip of the laser probe (Fig. 18, col. 12 line 62 – col. 13 line 5, col. 13 lines 24-28, col. 28 lines 39-67, col. 29 lines 1-14). The laser probe is interpreted to constitute a needle by the common definition of that term as set forth by Merriam Webster ("a slender pointed object resembling a needle").

FIG. 18

Source: Kami ('799); Drawings p. 11 of 35

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 3, 5 and 7-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kami ('799).

Regarding claims 2, 3, 8 and 9, Kami ('799) substantially teaches all features of the present invention as previously discussed for claims 1 and 4, but does not expressly teach the strain gauge to change resistance upon deflection, nor does Kami ('799) expressly teach the strain gauge to be within an electrical circuit as claimed. Examiner hereby takes Official Notice that it is known in the art to use a Wheatstone bridge (i.e., an “electrical circuit in which a potential difference occurs when the resistance of the strain gauge changes”) with a strain gauge to detect deflection of medical instruments. Accordingly, it would have been obvious to one of ordinary skill in the art to use a known Wheatstone bridge with the strain gauge of Kami ('799) in order to achieve the present invention, as such a combination of known prior art elements to yield predictable results has previously been held as unpatentable (see for precedent *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Regarding claim 5, Kami ('799) does not expressly teach a second strain gauge affixed to the laser probe. Applicant does not disclose that the additional strain gauge solves a particular problem, is used for a specific purpose, or presents a patentable advantage over prior art single-gauge arrangements. Furthermore, it has previously been held that the mere duplication of known elements is unpatentable

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over the prior art (see MPEP 2144, *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)). Accordingly, it would have been obvious to one of ordinary skill in the art to include a second strain gauge on the laser probe of Kami ('799) in order to achieve the presently claimed invention.

Regarding claims 7, 12 and 13, Kami ('799) teaches all features as discussed for claims 1 and 4, and further teaches an optical system that is capable of tracking the position of the laser probe (col. 19 lines 8-37, Fig. 38). Although Kami ('799) does not expressly teach the optical system for specifically tracking the laser probe, Kami ('799) does generally teach the optical system as being useful for performing surgery under precise observation. As such, a skilled artisan would find it obvious to use the optical system of Kami ('799) to track the laser probe, also of Kami ('799), during a surgical procedure in view of the teachings of Kami ('799).

Regarding claim 10, Kami ('799) includes a processing unit 128 that correlates the output of the strain gauge with an amount of movement of the laser probe (col. 13 lines 8-17).

Regarding claim 11, Kami ('799) includes an embodiment having a display that shows the medical instrument (Figs. 35 & 36).

Regarding claims 14-20, Kami ('799) teaches a method of using the system discussed for claims 1-13 including steps of tracking a medical instrument with an optical tracking system (col. 19 lines 8-37), and a method of tracking movement of the distal tip of the needle with the strain gauge (col. 12 line 62 – col. 13 line 5, col. 13 lines 24-28). Although Kami ('799) does not explicitly teach the use of these two methods together in a single procedure, it would have been obvious to one of ordinary skill in the art to do so in view of the teach of Kami ('799) the optical system is advantageous for realizing precise operations (col. 19 lines 11-12).

Regarding claims 21 and 22, the strain gauge of Kami ('799) provides information regarding a location of the deflectable operative distal tip in relation to a longitudinal axis of the support member as previously discussed for claim 1.

Regarding claim 23, Kami ('799) teaches that the deflection of the strain gauge indicates that the probe is in contact with tissue (col. 13 lines 1-6), which constitutes the provision of information regarding a location of the operative distal tip as claimed.

Response to Arguments

5. Applicant's arguments filed 20 Aug 2008 have been fully considered but they are not persuasive. Applicant challenges Kami ('799) for allegedly lacking a strain gauge that “is used to detect movement of

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the operative distal tip of the flexible engaging member” (Remarks p. 6 paragraph 6). Applicant points to col. 13 lines 1-6 of the reference to show that, because Kami ('799) uses the strain gauge to detect when the support member 123 operatively connected to a needle-tipped laser probe 122 (i.e., “a flexible engaging member”) is placed on a tissue, it does not meet the limitation of detecting movement of the operative distal tip of the flexible engaging member. Examiner maintains that detection of the laser probe coming into contact with tissue does in fact constitute detection of the movement of the operative distal tip of the flexible engaging member – the tip must inherently move in order to make contact with the tissue, thus detection of contact constitutes detection of movement.

Applicant additionally attacks Kami ('799) for purportedly lacking “a needle, catheter, curette [or] K wire” (Remark p. 7). As discussed in the previous Office Action and reiterated herein, the reference laser probe is interpreted to constitute a needle by the common definition of that term as set forth by Merriam Webster (“a slender pointed object resembling a needle”) (see Fig. 18 of Kami).

Applicant also argues the obviousness rejection of claim 5, specifically that Examiner’s rejection of the recited additional strain gauges as being obvious is improper in view of the disclosure at paragraphs 26-30. Applicant admits that Kami ('799) discloses multiple lateral pressure sensors that perform the same function as the recited strain gauges (Remarks p. 7 paragraphs 1-2). Applicant has not sufficiently shown that specifically using strain gauges provides any advantage over a general pressure sensor as taught by the prior art. Thus, the inclusion of multiple lateral strain gauges is in fact obvious over the prior art, for any one of the following reasons: obvious duplication of the prior art strain gauge, substitution of known equivalents (a strain gauge for pressure transducers), obvious matter of design choice (see also MPEP 2144.04 for precedent case law), or simply the fact that a skilled artisan would consider it a mere matter of common sense to arrive at the conclusion that placing strain gauges at multiple lateral positions would provide more detailed information about the directional disposition of the distal tip of the probe (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385). As Applicant has not disclosed a novel and inventive motivation for providing multiple strain gauges, the limitation remains obvious in view of Kami ('799).

Applicant additionally argues that the optical system of Kami ('799) does not meet all the limitations of the claimed optical tracking system, i.e. that the reference system illustrated in Fig. 38 does not show the laser probe. Kami ('799) explicitly states that “[i]ntraperative microscopes permitting surgery under microscopic observation realize precise operation... the intraoperative microscope allows a surgeon to proceed in a surgical procedure” (col. 19 lines 11-14). Through at least this disclosure, Kami ('799) clearly anticipates performing a surgical operation, including the one described elsewhere in the

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reference using the laser probe, under microscopic observation. As such, the reference is in fact found to meet the limitations of claims 7 and 20.

As Applicant's arguments are found to be wholly unpersuasive for at least the foregoing reasons, the previous rejection of claims 1-20 in view of Kami ('799) is maintained and reiterated herein. New claims 21-23 are additionally found to be unpatentable over Kami ('799) as discussed herein.

6. Applicant's amendments are sufficient to overcome the previous objection to claim 13, which is hereby vacated.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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3737

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Examiner, Art Unit 3737